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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,391	11/19/2003	Dean L. Engelhardt	Enz-52(C2)	9721

28171 7590 02/02/2010

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EXAMINER	
SALMON, KATHERINE D	
ART UNIT	PAPER NUMBER
1634	
MAIL DATE	DELIVERY MODE
02/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,391	ENGELHARDT ET AL.	
	Examiner	Art Unit	
	KATHERINE SALMON	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *91-103* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *91-103* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/08/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to papers filed 10/08/2009.

2. Currently Claims 91-103 are pending. Claims 1-90 have been cancelled.

3. The following rejections are reiterated with response to arguments following.

4. This action is Final.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 91-94 and 97-98 are rejected under 35 U.S.C. 102(b) as being anticipated by Scheele (US Patent 5162209 November 10, 1992).

With regard to Claim 91, step a, Scheele teaches providing a first DNA strand from genomic DNA (e.g. a nucleic sample containing the sequence of a specific sample) (column 3 lines 25 and Column 5 lines 30-35).

With regard to step b, Scheele teaches contacting the DNA with dNTPs (e.g. un modified nucleic acid precursors) (Column 4 lines 20-22). Scheele et al. teaches a primer sequence which is substantially complementary to the distinct sequence of said specific nucleic acid (Column 3 lines 33-40). Scheele teaches a method of adding E. coli DNA polymerase I (e.g. effective amount of nucleic acid producing catalyst) (column 4 lines 14-15).

Scheele. teaches a primer comprising an RNA segment (Column 3 lines 33-40). Scheele teaches a method of adding E. coli DNA polymerase I (e.g. effective amount of nucleic acid producing catalyst) (column 4 lines 14-15). Scheele teaches a method of adding RNase H (Column 4 lines 25).

With regard to step c, Scheele teaches a method of carrying out synthesis in the presence of the RNA primer to generate a polynucleotide comprising an RNA/DNA hybrid (Column 3 lines 30-40 and Figure 5).

With regard to step d, Scheele teaches a method of digesting the substrate with RNase H to remove the ribonucleic acid segment of the extended primer (Column 3 lines 30-40, column 4 lines 25-28, and Figure 5). Scheele teaches that the method can by adapted to permit amplification of the sample of dsDNA by PCR methodology (column 8 lines 58-60). Scheele teaches that the reagents of the RNA primer, DNA target, dNTPs and Taq are placed into a PCR machine with the appropriate number of PCR temperature cycles (column 8 lines 65-69). Therefore in a PCR cycle the resultant dsDNA of step c would be denatured such that multiple copies of the DNA could be copied from the DNA of interest.

The instant specification does not define isostatic conditions of temperature, buffer and ionic strength. Scheele teaches combining the primer and the DNA molecule in a reagent solution at a particular heat with buffers that have a particular ionic strength to produce at least one copy of the DNA molecule by extension

of the primer (Column 8 lines 1-15). Therefore Scheele teaches a method of allowing the mixture to react under isostatic condition of temperature, buffer, and ionic strength.

With regard to Claims 92-93, Scheele et al. teaches a method of removing the primer portion with RNase H (e.g. digestion with an enzyme) (column 4 lines 24-26).

With regard to Claim 94, Scheele et al. teaches a primer comprising an RNA segment (Column 3 lines 33-40).

With regard to Claim 97, Scheele et al teaches that the primer is comprises of a tail which is composed of nucleoside triphosphates (column 3 Table 1 and Column 4 lines 5-10). Scheele et al. teaches that that the triphosphate was radiolabel and as such was modified (column 8 lines 35-40).

With regard to Claim 98, Scheele teaches that the primer includes a portion of nucleotides that is complementary to an oligonucleotide tail added to the 3' end of the target DNA template (column 3 lines 25-35). Therefore the primers include a sequence which is complementary to the tail and therefore not complementary to the sequence of the DNA molecule of interest (e.g. the tail is added to the DNA target of interest but the tail is not considered the DNA which is of interest to be amplified) (Figure 5 and column 3 lines 25-40). Therefore Scheele et al. teaches primers which comprises about 1 to about 200 noncomplementary nucleotides.

Response to Arguments

The reply traverses the rejection. A summary of the arguments are provided below with response to arguments following.

(A) The reply asserts that the rejection does not provide that the primers be chemically modified (p. 12 last paragraph). The reply asserts that the teaching of labeling primers with radioactive labels would not lead one of skill in the art to consider the primers to be modified primers (p. 12 last paragraph). The reply asserts that there is a phosphorus moiety at each site regardless of whether it is a normal or radioactive version of P and thereby the labeled primer has the same chemical properties as an unlabeled primer (p. 12 last paragraph). The reply asserts that further, the Scheele's primer is not labeled but rather that the element is a radioactively labeled template used for binding and extension (p. 12 last paragraph). The reply asserts that after the extension reaction digestion of the unlabeled primer by RNAse H renders the Poly(dC) in ss form that is a substrate for exonucleolytic digestion by T4 (p 12 last paragraph). The reply asserts that therefore it is the removal of the radioactively labeled target and not the primer (p. 13 1st paragraph).

These arguments have been fully reviewed but have not been found persuasive.

The claims are drawn to "chemically-modified primers", however, the claims do not require that these primers to have the same or different chemical properties. Rather, these primers have a chemical attachment which is different from a nucleic acid without a chemical attachment. This attachment would be the radioactive label. The reply asserts that it is the target which is labeled not the primer. However, Scheele et al. teaches that the primer includes a portion of nucleotides that are complementary to an oligonucleotide tail (column 3 lines 25-35). Scheele et al. teaches that this tail comprising nucleoside triphosphates (column 3 table 1 and column 4 lines 5-10). The

method does not require that the chemically modified primer to be removed, but rather requires that the sample be contacted with a primer that has been chemically modified. This term is being broadly interpreted as requiring that the primer being present with a radioactive labeled nucleotide. Herein Scheele et al. teaches that the primer is mixed with a radioactive nucleotide (column 8 lines 5-40).

(B) The reply asserts that all of the steps are taking place under isostatic conditions and therefore the binding, extension, removal and binding of a new primer on a regenerated primer binding site are taking place simultaneously (p. 13 1st full paragraph).

This has been fully reviewed but has not been found persuasive.

The claims do not require that the steps be done simultaneously. Further the claims require that the steps be done under isostatic conditions of temperature, buffer, and ionic strength. However, the claims do not require that the isostatic conditions be identical in each step. Therefore Scheele et al. teaches performing steps a-d in solutions with particular temperature and buffers and as such teaches the requirements for the claim.

(C) The reply asserts that although Scheele uses an RNAse H step to remove primer sequences, the nucleotide acid sequence thereby rendered single stranded are not used for new primer binding events (p. 13 1st full paragraph). The reply asserts that Scheele teaches away from this method because he teaches the simultaneous

presence of a nuclease that will digest away the sequences that could otherwise provide a primer binding site (p. 13 1st full paragraph). The reply asserts that the RNase H digestion step does not provide means for amplification but is only used to render the ds nucleic acid into a blunt ended form (p. 13 1st full paragraph). The reply asserts that the thermal denaturation step of the PCR reaction of Scheele does not remove a portion of the primer but instead removes the entire extended nucleic acid (p. 13 1st full paragraph).

This argument has been fully reviewed but has not been found persuasive.

The reply seems to be asserting that the same primer binding event must occur, however, the claim has not been limited to such a step. Specifically step d requires digestion with RNase H wherein the removal allows for another DNA molecule to be produced. Herein in the instant case, Scheele et al. teaches the amplification via PCR. Scheele et al. teaches a sample of ds cDNA is prepared and added to its RNA primer with its DNA tail extension intact and excess RNA primers and excess oligo(dT). Taq and dNTPs are further added. The mixture is then subjected to PCR and the RNAse is added. As such Scheele et al. teaches that multiple copies of the DNA molecule of interest are produced. The applicant seems to be asserting that the main difference between Scheele et al. and the claimed method is that the claim method requires the addition of RNase H before multiple copies are produced. However, the claim has a larger breadth than this limitation. Step d only requires the digestion of the substrate with RNase H so that the substrate is capable of anther primer binding event to occur. The steps recited do not limit the last step to a positive recitation of removing the RNA

segment with RNase H and then producing another DNA molecule by performing steps a-d.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 95-96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheele (US Patent 5162209 November 10, 1992) in view of Gelfand et al. (US Patent 5374553 December 20, 1994).

Scheele teaches providing a first DNA strand from genomic DNA (e.g. a nucleic sample containing the sequence of a specific sample) (column 3 lines 25 and Column 5 lines 30-35).

Scheele teaches contacting the DNA with dNTPs (e.g. unmodified nucleic acid precursors) (Column 4 lines 20-22). Scheele et al. teaches a primer sequence which is substantially complementary to the distinct sequence of said specific nucleic acid (Column 3 lines 33-40). Scheele teaches a method of adding E. coli DNA polymerase I (e.g. effective amount of nucleic acid producing catalyst) (column 4 lines 14-15).

Scheele. teaches a primer comprising an RNA segment (Column 3 lines 33-40). Scheele teaches a method of adding E. coli DNA polymerase I (e.g. effective amount of nucleic acid producing catalyst) (column 4 lines 14-15). Scheele teaches a method of adding RNase H (Column 4 lines 25).

Scheele teaches a method of carrying out synthesis in the presence of the RNA primer to generate a polynucleotide comprising an RNA/DNA hybrid (Column 3 lines 30-40 and Figure 5). The instant specification does not define isostatic conditions of temperature, buffer and ionic strength. Scheele teaches combining the primer and the DNA molecule in a reagent solution at a particular heat with buffers that have a particular ionic strength to produce at least one copy of the DNA molecule by extension of the primer (Column 8 lines 1-15). Therefore Scheele teaches a method of allowing the mixture to react under isostatic condition of temperature, buffer, and ionic strength.

Scheele teaches a method of digesting the substrate with RNase H to remove the ribonucleic acid segment of the extended primer (Column 3 lines 30-40, column 4

lines 25-28, and Figure 5). Scheele teaches that the method can by adapted to permit amplification of the sample of dsDNA by PCR methodology (column 8 lines 58-60). Scheele teaches that the reagents of the RNA primer, DNA target, dNTPs and Taq are placed into a PCR machine with the appropriate number of PCR temperature cycles (column 8 lines 65-69). Therefore in a PCR cycle the resultant dsDNA of step c would be denatured such that multiple copies of the DNA could be copied from the DNA of interest.

However, Scheele et al. does not teach the modification of the primers to comprise an isosteric configuration of heteroatoms.

With regard to Claims 95-96, Gelfand et al teaches that to avoid primer degradation in PCR, phosphorothioate (e.g. comprises of sulfur heteroatom) can be added to the 3' ends of the primers to allow the primers to be more resistance to degradation (Column 13 lines 15-20).

Therefore it would be prima facie obvious to modify the in vitro translation method of Scheele et al. to have a phosphorothioate (sulfur heteroatoms) on the 3' end of the primers as taught by Gelfand et al. in order to maintain the primers during the PCR step of Scheele et al (column 8 lines 58-60) to produce multiple copies of the nucleic acid of interest. The ordinary artisan would be motivated to modify the primer of Scheele et al. to include the phosphorothioate (sulfur heteroatoms) of Gelfand et al., because Gelfand et al. teaches that the addition of phosphorothioate to the primers ends allows the primers to be more resistant to degradation (column 13 lines 15-20). Therefore the ordinary artisan would be motivated to modify the primers of Scheele et

al. to include the phosphorothioate (sulfur heteroatom) of Gelfand et al. because primers resistant to degradation can be maintained longer in a PCR and therefore more copies of the original nucleic acid may be produced.

Response to Arguments

The reply traverses the rejection. A summary of the arguments are provided below with response to arguments following.

The reply asserts that because Scheele et al. does not disclose or suggest the present invention than the addition of Gelfand et al. does not cure the deficiencies of Scheele et al. (p. 16 1st full paragraph).

This has been fully reviewed but has not been found persuasive.

As asserted above, it is the examiner's position that Scheele et al. teaches all the positive active recited limitations of the independent claims.

8. Claims 99-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scheele (US Patent 5162209 November 10, 1992) in view of Reischl et al. (US Patent 5474916 December 12, 1995).

With regard to Claim 99, step a, Scheele teaches providing a first DNA strand from genomic DNA (e.g. a nucleic sample containing the sequence of a specific sample) (column 3 lines 25 and Column 5 lines 30-35).

With regard to step b, Scheele teaches contacting the DNA with dNTPs (e.g. unmodified nucleic acid precursors) (Column 4 lines 20-22). Scheele et al. teaches a primer sequence which includes a portion of nucleotides that is complementary to an oligonucleotide tail added to the 3' end of the target DNA template (column 3 lines 25-

35). Therefore the primers include a sequence which is complementary to the tail and therefore not complementary to the sequence of the DNA molecule of interest (e.g. the tail is added to the DNA target of interest but the tail is not considered the DNA which is of interest to be amplified) (Figure 5 and column 3 lines 25-40). As such the primer comprises at least one noncomplementary nucleotide. However Scheele et al. does not teach the formation of a loop structure.

Scheele teaches a method of adding E. coli DNA polymerase I (e.g. effective amount of nucleic acid producing catalyst) (column 4 lines 14-15).

Scheele. teaches a primer comprising an RNA segment (Column 3 lines 33-40). Scheele teaches a method of adding E. coli DNA polymerase I (e.g. effective amount of nucleic acid producing catalyst) (column 4 lines 14-15). Scheele teaches a method of adding RNase H (Column 4 lines 25).

With regard to step c, Scheele teaches a method of carrying out synthesis in the presence of the RNA primer to generate a polynucleotide comprising an RNA/DNA hybrid (Column 3 lines 30-40 and Figure 5). The instant specification does not define isostatic conditions of temperature, buffer and ionic strength. Scheele teaches combining the primer and the DNA molecule in a reagent solution at a particular heat with buffers that have a particular ionic strength to produce at least one copy of the DNA molecule by extension of the primer (Column 8 lines 1-15). Therefore Scheele teaches a method of allowing the mixture to react under isostatic condition of temperature, buffer, and ionic strength.

With regard to step d, Scheele teaches a method of digesting the substrate with RNase H to remove the ribonucleic acid segment of the extended primer which would include the tail portion of the primer (Column 3 lines 30-40, column 4 lines 25-28, and Figure 5). Scheele teaches that the method can by adapted to permit amplification of the sample of dsDNA by PCR methodology (column 8 lines 58-60). Scheele teaches that the reagents of the RNA primer, DNA target, dNTPs and Taq are placed into a PCR machine with the appropriate number of PCR temperature cycles (column 8 lines 65-69). Therefore in a PCR cycle the resultant dsDNA of step c would be denatured such that multiple copies of the DNA could be copied from the DNA of interest.

With regard to Claims 100-101, Scheele et al. teaches a method of removing the primer portion with RNase H (e.g. digestion with an enzyme) (column 4 lines 24-26).

With regard to Claim 102, Scheele et al. teaches a primer comprising an RNA segment (Column 3 lines 33-40).

With regard to Claim 103, Scheele teaches that the primer includes a portion of nucleotides that is complementary to an oligonucleotide tail added to the 3' end of the target DNA template (column 3 lines 25-35). Therefore the primers include a sequence which is complementary to the tail and therefore not complementary to the sequence of the DNA molecule of interest (e.g. the tail is added to the DNA target of interest but the tail is not considered the DNA which is of interest to be amplified) (Figure 5 and column 3 lines 25-40). Therefore Scheele et al. teaches primers which comprises about 1 to about 200 noncomplementary nucleotides.

However, Scheele et al. does not teaches a method wherein the primers form a loop structure which is removed from the complementary copy.

With regard to Claim 99, Reischl et al teaches a method wherein the primer comprises a loop structure at the end which is used by the polymerase as an initiator site to synthesis the DNA structure (Colum 12 lines 60-66-Column 13 lines 1-10). Therefore it would be obvious to modify the tail portion of the primer of Scheele et al. to include a loop structure which upon hybridization to the template would be used as an initiator site for synthesis. Scheele et al. teaches that the primer is then digested with RNASH and therefore the loop structure would be removed form the complementary strand.

Therefore it would be prima facie obvious to one of ordinary skill in the art to modify the teachings of Scheele et al. such that a primer with a loop on the end is used to synthesis DNA as taught by Reischl et al. The ordinary artisan would be motivated to add a loop to the primer structure of Scheele et al. because Reischl et al. teaches that this loop contains a region for the polymerase to start making a complementary copy of the structure (Colum 12 lines 60-66-Column 13 lines 1-10). Therefore the ordinary artisan would be motivated to have a loop structure so that the polymerase has an initial starting point for transcription and removing the loop structure along with the rest of the primer with RNAse H after synthesis in order to allowing for a new strand to be synthesized. .

Response to Arguments

The reply traverses the rejection. A summary of the arguments made in the reply is provided below with response to arguments following.

The reply asserts that although Scheele teaches that digestion by RNAse H of an RNA primer can render a template single stranded, Scheele does not teach the use of the single stranded portion created by this process as being used as a primer binding site (p. 18 last paragraph).

These arguments have been fully reviewed but have not been found persuasive.

As stated above, the claims are not limited to the production of the second copy of the nucleic acid by the steps of a-d. Rather the claims are limited to the production of multiple copies of the nucleic acid and the removal of loop structures.

The reply asserts that Scheele et al. does not teach a loop (p. 18 last paragraph-p. 19 1st paragraph). The reply asserts that the loop of Reischl et al. would not be combined as it is not certain how RNAse H would remove the loop portion because RNAse H has no affinity for ss DNA (p. 19 2nd paragraph). The reply asserts that the loop of Resichel is preexisting and is not formed upon hybridization. (p. 19 2nd paragraph). The reply asserts that there is no explanation as to why the digestion of the tail that contains a noncomplementary loop would promulgate another primer binding event (p. 19 2nd paragraph).

These arguments have been fully reviewed but have not been found persuasive.

The claim does not require RNAse H. Further the RNAse H is not digesting the loop portion but rather it would digest the tail end of which the loop is at the end. Once

this portion is digested the loop would be removed from the complex. The reply asserts that the loop must be formed at the point of hybridization. However, the loop of Reischl et al. is formed at the point of hybridization. Reischl et al. teaches the P1 nucleotide promotion (e.g. the loop structure) has a single stranded region that is either not at all or only to a limited extent complementary to the template (column 4 lines 1-30). As such this region that has a loop upon hybridization to the template is not completely complementary to the template so the region that is not complementary forms the loop structure.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE SALMON whose telephone number is

(571)272-3316. The examiner can normally be reached on Monday - Friday 9AM-530PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Salmon

/Sarae Bausch/
Primary Examiner, Art Unit 1634